



NATURAL HEALTH PRODUCT

ALOE - *ALOE VERA*

Oral

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 31, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common names(s)	Source material(s)	
		Proper name(s)	Part(s)
<i>Aloe vera</i>	<ul style="list-style-type: none"> ▶ Aloe ▶ Aloe vera ▶ Barbados aloe ▶ Curaçao aloe ▶ True aloe ▶ West Indian aloe 	<i>Aloe vera</i>	Leaf Latex

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin et al. 2000; Source material: Barnes et al. 2007, Williamson 2003.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.



Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ [(Traditionally) used in Herbal Medicine as a] stimulant laxative (Williamson 2003; Bradley 1992; Felter and Lloyd 1983; Grieve 1971).
- ▶ (Used in Herbal Medicine for the) short-term relief of occasional constipation (EMEA 2006).
- ▶ (Used in Herbal Medicine to) promote(s) bowel movement (by direct action on the large intestine) (Sweetman 2007; EMEA 2006; WHO 1999).

The following combined use(s) or purpose(s) is/are also acceptable:

(Used in Herbal Medicine as a) stimulant laxative for short-term relief of occasional constipation (EMEA 2006).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine” or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adolescents 12 to 17 years and adults 18 years and older (EMEA 2006; Brinker 2001).

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

50 - 300 milligrams dried leaf latex, per day (Williamson 2003; Bradley 1992)

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

10 - 30 milligrams hydroxyanthracene derivatives (calculated as barbaloin/aloin), per day (Barnes et al. 2007; EMEA 2006; Blumenthal et al. 1998)



Direction(s) for use

- ▶ Allow at least 6-12 hours for laxative effect to occur (EMEA 2006; Berardi et al. 2002).
- ▶ Take a single dose at bedtime, a few hours before or after taking other medications or health products, two to three times per week. Frequency of use may be increased up to once daily if results are not observed (EMEA 2006; McGuffin et al. 1997; Bradley 1992).

Optional (for products which provide a dosage range):

The correct individual dose is the smallest one required to produce a soft-formed stool (EMEA 2006).

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 7 days (EMEA 2006; Brinker 2001).

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a kidney disorder, or are taking cardiac medications (e.g. cardiac glycosides or antiarrhythmic medications) (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking thiazide diuretics, corticosteroids, licorice root, or other medications or health products that may aggravate electrolyte imbalance (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- ▶ Reduce dose or stop use if you experience abdominal pain, cramps, spasms and/or diarrhoea (EMEA 2006; Brinker 2001).



Contraindication(s)

- ▶ Do not use this product if you have abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, hemorrhoids or diarrhoea (Brinker 2018; EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- ▶ Do not use this product if you are pregnant or breastfeeding (Brinker 2001; McGuffin et al. 1997).

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Brinker 2018; EMEA 2006).

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the specifications outlined in the NHPID.

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